

**PATENT**/Docket No. 6267.N

Serial No. 09/836804

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**REMARKS**

The Office Action mailed February 17, 2004 has been received and reviewed. Claims 6 and 12 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner stated that the previously amended claims 6 and 12 are deemed to insert new matter because "the specification as originally filed does not provide support for the negative limitation, 'said mammal is not suffering from an bacterial infection'."

Applicants respectfully disagree with the Office's position. Claims 6 and 12 as originally filed were read as followings:

"6. The method according to claim 1 wherein said mammal is not suffering from an antibacterial infection."

"12. The method according to claim 7 wherein said mammal is not suffering from an antibacterial infection."

In the previous amendment, applicants were merely correcting the typo errors to remove the prefix "anti" from claims 6 and 12. As specified in US patent law, claims as originally filed are the part of the specification of the patent application. For this reason, applicants submit that the rejections of the instant claims should be reconsidered and withdrawn.

The Office has rejected claims 1 - 6 under 35 USC 103(a) over Hester et al. in view of Nair et al. The Office finds that Hester et al. discloses the antibacterial activity of the compounds of this invention and that Nair et al. discloses that certain bacterial infections are associated with bone loss. The Office concludes that it would have been obvious to treat bacterial infections with the compounds of this invention to treat bone loss associated with such bacterial infections.

In order to expedite the prosecution, applicants have cancelled claims 1-6. As such, this rejection is considered moot in view of these cancellations to claims 1-6. Applicants reserve the right to file a continuation application directed to the now cancelled subject matter.

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The Office has further rejected claims 7 - 12 under 35 USC 103(a) over Yoshida et al. in view of Nair et al. The Office finds that Yoshida et al. describes that certain compounds within the instant claims have antibacterial activity and that together with Nair et al. suggest the use of these compounds to treat bacterial infections associated with bone loss. In order to expedite the prosecution, applicants have amended claim 7. The amended claim 7 does not contain any subject matter that was described in Yoshida et al. The rejection under this ground relies on the secondary reference, Nair et al., to establish that bacteria are known to be an important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss. The Office then concludes that it would have been obvious to employ antibacterial agents to treat osteoporosis, bone resorption, or other bone diseases. Applicants traverse their rejections for the following reason.

Nair et al. is a review that discusses the cellular and molecular mechanisms involved in the bacterially induced skeletal pathologies of periodontitis, osteomyelitis, bacterial arthritis, and infected metal implants. Nair et al. does not teach, suggest, or conclude that antibacterial agents would be useful in the treatment of such diseases, however. Rather, Nair et al. concludes by stating that the further understanding of the pathogenetic mechanisms could provide useful therapeutic targets for the development of new treatment modalities. Thus applicants submit that Nair et al. not only does not teach or suggest the use of antibiotics for the treatment of certain bacterially related bone diseases but applicants submit that Nair et al. teaches away from such a conclusion.

Whether or not treatment of the bacterial infections might be useful in the treatment of such bacterially-related bone diseases by reducing or eliminating associated bacteria, applicants' invention is not directed to the treatment of bone loss caused by bacteria, but rather, applicants' discovery is that certain compounds, albeit previously known to have antibacterial activity, also possess the ability to enhance bone growth, presumably by preventing bone resorption, and thus are useful in the treatment of many conditions associated with bone loss. Indeed, one of the embodiments of applicants' invention is the treatment of bone diseases where no bacterial infection is present (see claim 6). Thus applicants' discovery is that the compounds of the claims

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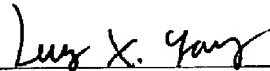
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of this application are useful in treating a variety of conditions, many of which have no relationship to bacteria.

Further, Nair et al. notes in its introduction that the bone diseases osteoporosis, rheumatoid arthritis, and osteoarthritis, are idiopathic and thus it can not be concluded that these conditions are caused by bacterial infection. Applicants submit that it would be illogical to conclude that antibacterial agents might be useful in the treatment of idiopathic diseases, not known to have a bacterial causative component.

In view of the amendment and the forgoing arguments, applicants thus conclude that the art does not teach or suggest that the compounds of the instant claims would be useful in the treatment of diseases associated with bone loss by enhancing bone growth. For this reason, applicants submit that the rejections of the instant claims should be reconsidered and withdrawn.

Applicants respectfully submit that the remaining claims are patentable and request that the outstanding rejections of the claims of this application be reconsidered and withdrawn. Applicants await an early favorable indication regarding the allowability of this application. Respectfully submitted,



Lucy X. Yang, Attorney  
Registration No. 40,259

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Pharmacia & Upjohn Company  
Global Intellectual Property  
301 Henrietta Street  
Kalamazoo, Michigan 49001

Telephone No. (269) 833-9536 or (269) 833-9500  
Telefax No. (269) 833-8897 or (269) 833-2316

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